

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
Petitioner,

v.

THE FOUNDRY, LLC,
Patent Owner.

IPR2024-00669
Patent 11,679,077 B2

Before SHERIDAN K. SNEDDEN, SUSAN L. C. MITCHELL, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Neurent Medical Inc. and Neurent Medical Ltd. (collectively “Petitioner”) filed a Petition (Paper 3, “Pet.”) requesting *inter partes* review of claims 1–8 and 11 of U.S. Patent No. 11,679,077 B2 (Ex. 1001, “the ’077 patent”). Pet. 8. The Foundry, LLC (“Patent Owner”) filed a Preliminary Response (Paper 7, “Prelim. Resp.”).

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless it is determined that there is a reasonable likelihood that the petitioner will prevail with respect to at least one of the claims challenged in the petition. For reasons explained below, we conclude that Petitioner shows a reasonable likelihood that it will prevail with respect to at least one of the ’077 patent’s challenged claims. Also, we decline to deny the Petition on a discretionary basis. Therefore, we institute an *inter partes* review on all challenged claims. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018).

Findings and conclusions at this stage are preliminary and based on the current record. Any final decision will be based on a full trial record.

II. BACKGROUND

A. *Real Parties-in-Interest*

Petitioner identifies Neurent Medical Inc. and Neurent Medical Ltd. as the real parties-in-interest. Pet. 2. Patent Owner identifies itself as the owner of the ’077 patent and identifies Aerin Medical Inc. as the patent’s exclusive licensee “in the field of medical device treatments of the nasal cavity for any purpose.” Paper 6, 2.

B. *Related Matters*

The parties identify the following lawsuit involving assertion of the ’077 patent (and related patents): *Aerin Medical Inc. and The Foundry LLC*

v. Neurent Medical Inc. and Neurent Medical Ltd., 1:23-cv-00756-JLH
(D. Del.); Pet. 3; Paper 6, 2.

Petitioner also identifies as related the following additional matters before the Board, as set forth in the table below:

Challenged Patent	Patent Owner	Case No.
9,072,597	Aerin Medical Inc.	IPR2024-00275
9,415,194	Aerin Medical Inc.	IPR2024-00276
11,241,271	Aerin Medical Inc.	IPR2024-00277
11,033,318	Aerin Medical Inc.	IPR2024-00278
10,610,675	The Foundry LLC	IPR2024-00279
10,894,011	The Foundry LLC	IPR2024-00280
11,679,077	The Foundry LLC	IPR2024-00281 ¹
11,766,286	Aerin Medical Inc.	IPR2024-00282

Pet. 3; Paper 5, 2 (identifying IPR2024-00279, IPR2024-00280, and IPR2024-00281).

C. The '077 Patent (Ex. 1001)

The '077 is titled “Systems and Methods for Delivery of a Therapeutic Agent.” Ex. 1001, code (54). The '077 patent issued June 20, 2023, from an application filed January 19, 2021, and names Mark E. Deem and Hanson Gifford as inventors. *Id.* at codes (22), (45), (72). The patent identifies and purports to claim the priority benefit of several previously-filed non-provisional applications and at least one provisional application, which was filed July 22, 2005. *Id.* at code (60), 1:6–32.

¹ Petitioner’s challenge in IPR2024-00281 was refiled before any decision on institution. The refiled matter is now the present case, IPR2024-00669. IPR2024-00281 has since been terminated. IPR2024-00281, Paper 10.

According to the '077 patent, “certain neurotoxins have found widespread use in millions of patients worldwide for a variety of conditions.” *Id.* at 1:50–52. The patent states that neurotoxins have been proposed for controlling rhinorrhea and other conditions. *Id.* at 2:23–52. The patent explains that “[r]hinorrhea is the term describing the effluence of mucus from the lining of the nasal passages, nasopharynx, or paranasal sinuses” and “can be a symptom of a number of diseases such as the common cold, sinusitis or rhinitis.” *Id.* at 7:44–51 (“Rhinitis (inflammation of the airways) falls into two major categories—allergic and non-allergic (or vasomotor) rhinitis”); *see also id.* at 3:13–16 (“rhinitis, which includes the symptoms of rhinorrhea, is a condition resulting from inflammation and swelling of the patient’s mucus membranes which line the nasal cavity”).

The '077 patent states that “[d]ue to their extreme toxicity, neurotoxins are highly controlled and can have disastrous consequences if not used and controlled properly, especially when used in vivo.” Ex. 1001, 2:58–60. Thus, the patent explains that

it would be desirable to provide improved methods and systems for delivering toxins, such as botulinum and active botulinum fragments, to the nasal membrane of a patient, particularly a patient suffering from rhinitis or other conditions associated with nasal inflammation and conditions, such as sinus headaches and migraine headaches. The methods and systems should be capable of providing for selective and repeatable delivery of the toxins to defined target areas within the nasal cavities, including particular paranasal sinuses, the nasopharynx, and in some cases substantially the entire nasal cavity. The systems and methods should provide for the safe and effective delivery of the toxins, and in particular should reduce or eliminate the risk of toxin being delivered to non-targeted tissues outside of the nasal cavity.

Id. at 3:56–4:3.

The '077 patent discloses that “[t]he present invention relates to methods and apparatus for the control of autonomic nerve function comprising delivery via permeabilization of targeted cell membranes a therapeutically effective amount of a portion or fragment of a neurotoxin,” and “[m]ore particularly, the present invention relates to methods and systems for delivering toxins, such as botulinum toxin light chain fragments, to target cells in a nasal cavity.” Ex. 1001, 1:38–47. According to the patent,

[a] further aspect of the invention is to provide methods and apparatus for treating or inhibiting a variety of diseases or syndromes that have an underlying neurogenic component, by disrupting the neurogenic activities of the promoters or mediators of the disease or syndrome. Such disruption is facilitated by delivering an active fragment of botulinum toxin, such as the light chain portion of botulinum toxin serotype A (BoNT-LC/A), in the presence of an electric field or ultrasonic energy applied to permeabilize the wall of targeted cell under conditions which induce reversible poration of the cellular membrane and efficient passage of the BoNT-LC fragment to the cell cytosol, its catalytic environment.

Id. at 4:66–5:11.

The '077 patent describes delivering neurotoxins and active fragments thereof “to a patient’s nasal membrane while applying energy to target cells within the membrane under conditions which cause a reversible (or in some instances non-reversible) poration of the cell membranes to enhance delivery of the toxin into the cells.” Ex. 1001, 8:10–18. According to the patent, the toxin may be introduced to “any portion of the nasal cavity, such as a single paranasal sinus or portion thereof, a main nasal passage, two or more paranasal sinuses,” “the entire nasal cavity of the patient,” or the “nasopharynx which is at the back of the nasal passage” and “comprises a

cluster of goblet cells which are responsible for mucus secretion and which are susceptible to the disabling mechanism of the botulinum toxin and other neurotoxins.” *Id.* at 8:18–28. The patent reports that, in the targeted nasal tissues, “a high percentage of mucus-secreting epithelial or goblet cells can be treated with a device which is relatively small and which may carry a relatively low infusion volume and require less energy.” *Id.* at 24:4–11.

The ’077 patent describes systems comprising “catheter[s] or other structure[s] adapted to introduce the toxin or toxin fragment to a region adjacent the target cells,” “an energy applicator for applying energy to the target cells under condition[s] which cause poration of the cell membranes to enhance delivery of the toxins and/or their active fragments,” and “a source of the toxin or active fragments suitable for introduction from the catheter or other delivery structure.” Ex. 1001, 5:18–26. According to the patent, “[t]he energy applicator will typically be adapted to selectively apply energy to target cells within the region where the toxin is to be introduced, e.g., by focusing energy distribution to the particular target cells or regions which are rich with the target cells,” but “may be adapted to apply energy non-selectively within the target region where both target cells and other cell types may receive the energy.” *Id.* at 5:27–34. The energy applicator may apply electric energy (such as radiofrequency (RF) energy, direct current, alternating current, or combinations thereof), ultrasonic energy (such as high acoustic pressure ultrasound or low acoustic pressure ultrasound), X-ray beam energy, microwave energy, or “any other energy type which can achieve a reversible poration of the target cell walls.” *Id.* at 5:42–52.

D. Illustrative Claims

Claims 1–8 and 11 are challenged in the Petition. Claim 1 is the only independent claim that is challenged. It reads:

1. An apparatus for treating rhinitis in a nasal cavity, the apparatus comprising:
 - an elongate body, comprising:
 - a proximal portion; and
 - a distal portion configured for positioning in the nasal cavity;
 - multiple radiofrequency electrodes coupled with the distal portion of the elongate body; and
 - a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.

Ex. 1001, 27:44–28:7.

To illustrate the subject matter of some of the challenged dependent claims, we summarize claims 2, 6, and 11, each of which depends from claim 1. Claim 2 adds that “the multiple radiofrequency electrodes comprise at least two bipolar radiofrequency electrodes.” *Id.* at 28:8–10. Claim 6 adds that “at least one of the multiple radiofrequency electrodes is movable relative to the distal portion of the elongate body.” *Id.* at 28:17–19. And claim 11 recites that the apparatus further comprises “a monitoring system coupled with the distal portion of the elongate body for monitoring a degree of treatment of the target tissue.” *Id.* at 28:33–36.

E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–8 and 11 are unpatentable based on the following grounds:

Grounds	Claim(s) Challenged	35 U.S.C. §²	Reference(s)/Basis
1	1–3, 5–8, 11	102	Saadat ³
2	3, 11	103	Saadat
3	4	103	Saadat, Stern ⁴
4	1–8, 11	102	Deem ⁵
5	1–3, 5–8, 11	103	Makower, ⁶ Fang, ⁷ Edwards ⁸
6	4	103	Makower, Fang, Edwards, Stern

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284, 285–88 (2011), revised 35 U.S.C. §§ 102, 103 effective March 16, 2013. We apply the AIA versions of §§ 102 and 103 based on our present determination of the priority date for the claims, as discussed below.

³ Saadat, US 10,307,200 B2, issued June 4, 2019 (Ex. 1003 (“Saadat”)).

⁴ Stern et al., US 5,562,720, issued Oct. 8, 1996 (Ex. 1009 (“Stern”)).

⁵ Deem et al., US 2008/0021369 A1, publ. Jan. 24, 2008 (Ex. 1004 (“Deem”)).

⁶ Makower et al., US 2005/0240147 A1, publ. Oct. 27, 2005 (Ex. 1005 (“Makower”)).

⁷ Fang and Zhen, *Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis*, 25(7) J. FIRST MIL. MED. UNIV. 876–77 (2005) (Ex. 1006 (“Fang”)).

⁸ Edwards, US 6,517,535 B2, issued Feb. 11, 2003 (Ex. 1008 (“Edwards”)).

Among other evidence, Petitioner also relies on testimony from Dr. Nicolas Bu-Saba (Exs. 1002 and 1083) and Dr. Gregory T. Martin (Exs. 1007 and 1084) in support of its challenges.

III. EXERCISE OF DISCRETION

Institution of an *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”). The Board may, for example, deny institution on a discretionary basis where a petitioner relies on “the same or substantially the same prior art or arguments previously presented to the Office.” 35 U.S.C. § 325(d); *see Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8, 10 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”) (establishing the Board’s two-step framework that informs whether § 325(d) discretionary denial is warranted).

Patent Owner argues that we should exercise our discretion under § 325(d) and deny institution because substantially the same prior art was previously presented to the Patent Office. Prelim. Resp. 26–33. Patent Owner’s argument for discretionary denial is, however, premised on a determination that Saadat is not prior art, and Patent Owner only addresses whether some of the prior art asserted under Grounds 4–6 was previously considered by the Office. *Id.* (addressing only the Examiner’s earlier

consideration of Makower and Fang (allegedly cumulative to Makower) during prosecution of a related patent).⁹

As discussed below (Section IV.D), we determine at this stage that Saadat is prior art. There is no argument from Patent Owner that Saadat was presented previously to the Office. Pet. 96 (Petitioner’s unrebutted argument that Saadat was not previously considered by the Examiner). And, beyond the unsuccessful attempt to antedate and, thus, disqualify Saadat as prior art, at this stage of the proceeding Patent Owner offers no argument or evidence to rebut Petitioner’s contention that Saadat anticipates and renders obvious the ’077 patent’s claims under Grounds 1–3. *See generally* Prelim. Resp. 8–26 (Patent Owner’s priority date arguments).

For the above reasons, we find that Patent Owner has not shown that substantially the same prior art or arguments (i.e., Saadat and arguments based thereon) were previously presented to the Office and, thus, Patent Owner has not satisfied step one of *Advanced Bionics*’ two-step framework. *Advanced Bionics*, Paper 6 at 8. On this record, even if we accept Patent Owner’s contentions about the Office’s prior consideration of Makower or Fang (art asserted under Grounds 5 and 6), we do not find that § 325(d) is sufficiently implicated based on our determination on the priority issue and Petitioner’s otherwise uncontested argument that the challenged claims are unpatentable over Saadat—issues we discuss in more detail below.

⁹ Patent Owner lists Ground 4 (anticipation by Deem) in its argument for discretionary denial, but never substantively addresses that ground or Deem as part of its argument. Prelim. Resp. 26 n.9. Although Deem does appear among the many references cited on the ’077 patent (Ex. 1001, code (56)), Deem’s citation does not change the result here because there is no argument or evidence to show that Saadat was considered previously by the Office.

Discretionary denial of the petition is, therefore, inappropriate on the record before us.

IV. ANALYSIS

A. *Legal Standards*

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3)).

Anticipation is a question of fact. *In re NTP, Inc.*, 654 F.3d 1279, 1297 (Fed. Cir. 2011). “Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements arranged as in the claim.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (internal quotation marks omitted). Whether a reference anticipates a claim is assessed from the skilled artisan’s perspective. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003) (“[T]he dispositive question regarding anticipation [i]s whether one skilled in the art would reasonably understand or infer from the [prior art reference’s] teaching that every claim element was disclosed in that single reference.” (quoting *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991))).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time the invention was

made¹⁰ to a person having ordinary skill in the relevant art. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations (i.e., objective indicia) of nonobviousness when presented.¹¹ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). “An obviousness determination [also] requires finding both that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *CRFD Rsch., Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (internal quotation marks and citation omitted).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the problems encountered in the art, the art’s solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner proposes that the person of ordinary skill in the art (“POSA”) at all relevant times (between the years 2005 through 2019) would have had:

¹⁰ The AIA revised § 103 such that obviousness is assessed “before the effective filing date of the claimed invention,” but *KSR* and other obviousness precedents cited herein remain applicable despite this change in the timing of the obviousness inquiry.

¹¹ The parties do not present argument on objective indicia at this stage.

(1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue. Less work experience may be compensated by a higher level of education, and vice versa.

Pet. 17–18 (citing Ex. 1002 ¶¶ 26–27; Ex. 1007 ¶¶ 24–28).

Patent Owner does not propose an alternate definition of the POSA’s qualifications or contest Petitioner’s definition. *See generally* Prelim. Resp.

We apply Petitioner’s proposed POSA level, which appears to be consistent with the level of skill shown in the prior art of record. *See Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

C. Claim Construction

In *inter partes* review, we construe claims using the same claim construction standard used to construe claims in a civil action before the courts under 35 U.S.C. § 282(b), including construing claims’ language in accordance with its ordinary and customary meaning as understood by the POSA, in view of the patent’s specification and considering the patent’s prosecution history. 37 C.F.R. § 42.100(b). We need only construe terms that are in controversy and only to the extent needed to resolve the controversy. *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019); *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (holding claim construction is for “resolution of disputed meanings”).

Petitioner contends that, “[f]or purposes of this IPR, the Board need not construe any terms.” Pet. 18. Patent Owner similarly does not propose any express claim construction for any of the challenged claims at this time. *See generally* Prelim. Resp.

Absent a dispute about the interpretation of the claims at this stage and based on our review of the record, we determine that no express construction of any claim term is necessary to determine whether to institute *inter partes* review. *Realtime Data*, 912 F.3d at 1375.

D. Effective Filing Date of the Challenged Claims

Petitioner contends that the priority date for the challenged claims is October 22, 2019, which is the filing date of the grandparent application (U.S. Application No. 16/659,893 (“the ’893 Application”)) to which the ’077 patent claims priority.¹² Pet. 18–26; Ex. 1001, code (60). The ’893 Application issued as U.S. Patent No. 10,610,675 (“the ’675 patent”). Ex. 1021. Patent Owner disagrees with Petitioner’s contentions about the priority date and argues the claims are, instead, entitled to an effective filing date at least as early as July 21, 2006. Prelim. Resp. 8–25 (arguing the claims are entitled to a priority date of July 21, 2006, the filing date of U.S. Application No. 11/459,090 (“the ’090 Application”), which application issued as U.S. Patent No. 7,608,275 (“the ’275 patent”)).

Having considered the parties’ positions and evidence of record, we determine, at this stage of the proceeding, that the applications in the ’077 patent’s putative priority chain (including the ’893 Application and earlier-filed applications) do not provide sufficient written description support for the challenged claims. Accordingly, for the purposes of this decision, we determine that the challenged claims are entitled to an effective filing date no earlier than October 22, 2019, the filing date of the

¹² The priority date dispute addressed in this section determines whether Saadat (asserted in Grounds 1–3) and Deem (asserted in Ground 4) qualify as prior art to the claims. Petitioner’s Grounds 5 and 6, in contrast, assumes an earlier effective priority date. Pet. 6–7.

'893 Application—the grandparent to the application that issued as the '077 patent. Our analysis follows.

1. The '077 Patent's Priority Information

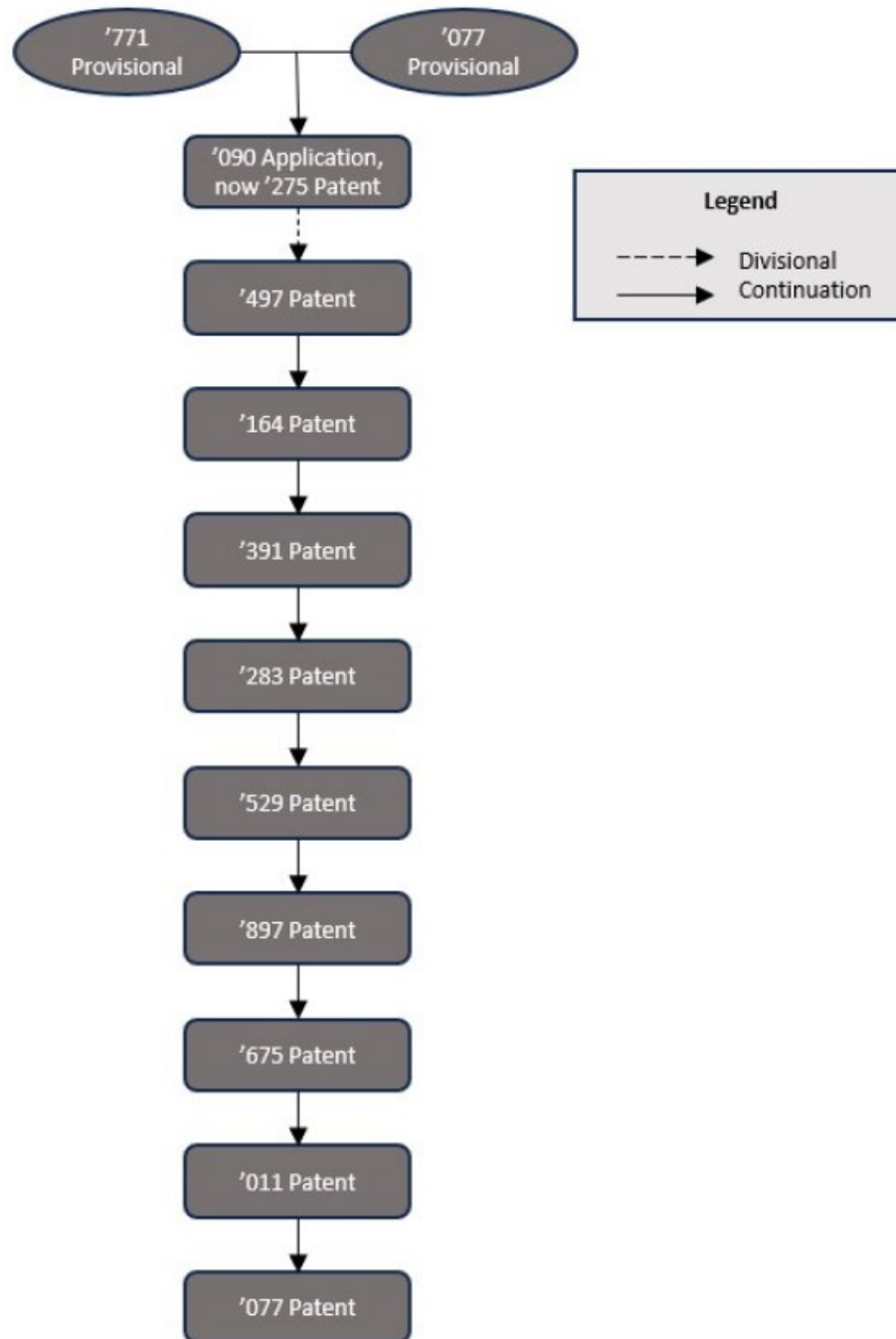
The '077 patent claims the priority benefit of a parent application, the grandparent '893 Application, and seven additional, earlier-filed non-provisional utility applications—the earliest of which is the '090 Application filed July 21, 2006. Ex. 1001, code (60);¹³ *see also* Prelim. Resp. 23 (diagram of family tree provided by Patent Owner). In addition, the '077 patent claims the priority benefit of U.S. Provisional Application No. 60/702,077 (“the '077 Provisional”), filed July 22, 2005.

Although the '077 patent does not expressly claim the priority benefit of U.S. Provisional Application No. 60/747,771 (“the '771 Provisional”) filed on May 19, 2006, the '077 patent states that the related '275 patent (i.e., the '090 Application) “claims the benefit of, and incorporated by reference in its entirety” the '771 Provisional.¹⁴ Ex. 1001, 1:28–32. “[T]hereby,” the '077 patent states, the '771 Provisional is “also fully incorporated [into the '077 patent] by reference.” *Id.*

We reproduce below a diagram provided by Patent Owner that purports to show the relationship between the '077 patent and the earlier-filed applications (and patents issuing therefrom) as discussed above.

¹³ Exhibits 1012–1017, 1019, 1021, and 1023, are copies of the patents that issued on non-provisional applications to which the '077 patent claims priority. The '893 Application issued as the '675 patent (Ex. 1021) and the '090 Application issued as the '275 patent (Ex. 1012).

¹⁴ Petitioner argues, with no rebuttal from Patent Owner, that the '077 patent cannot claim priority to the filing date of the '771 Provisional absent a formal claim of priority that appears in the patent's application data sheet. Pet. 21 (citing, *inter alia*, 37 C.F.R. § 1.78(a)(3)).



Prelim. Resp. 23. As shown in the diagram above, the '077 Provisional and '771 Provisional appear at the top joined by a horizontal line; from that horizontal line, an arrow points downward to the '090 Application (now the '275 patent), and further arrows point downward from each successive

issued patent (e.g., the '675 patent/'893 Application) before ending at the '077 patent at the bottom.

2. *Petitioner's Contentions*

Petitioner makes several arguments to support its position that the priority date for the challenged claims is no earlier than October 22, 2019, the filing date of the grandparent '893 Application (i.e., the '675 patent). Pet. 18–26.

First, Petitioner contends that the '077 Provisional and all intervening non-provisional applications in the '077 patent's priority chain preceding the '893 Application described methods of using a neurotoxin to treat the bronchial tubes or use of neurotoxin for cosmetic applications, not methods and an apparatus for treating the nasal passage or rhinitis with RF energy as claimed. *Id.* at 1, 19–21. According to Petitioner, Patent Owner, with its filing of the '893 Application, inserted new matter from a different provisional application—the '771 Provisional¹⁵—into the specification of the '893 Application in an attempt to add written description support for a wholly different category of claims; it was only then, Petitioner argues, that Patent Owner began pursuing claims to treating nasal conditions with energy. *Id.* (asserting that the alleged new matter was then repeated in the applications that followed the '893 Application, including the application that issued as the '077 patent).

Second, Petitioner contends that, absent a formal priority claim, the '077 patent is not entitled to the priority benefit of the '771 Provisional's filing date. *Id.* at 21 (citing Ex. 1025 (file history of the '077 patent), 1–8)).

¹⁵ The '771 Provisional is titled “Methods and Systems for Toxin Delivery to the Nasal Cavity.” Ex. 1011, 27.

Petitioner notes that, although some applications in the '077 patent's priority chain claim priority to the '771 Provisional, some do not. *Id.* at 21–22 (comparing priority chains of the '283 patent (Ex. 1016) and the '529 patent (Ex. 1017)). And, Petitioner contends, some (but not all) of the earlier applications only incorporate the '771 Provisional by reference. Prelim. Resp. 21–22 (asserting that, in the two applications immediately preceding the '893 Application, the '771 Provisional is neither the subject of a priority claim nor incorporated by reference). Thus, Petitioner contends, the priority chain to the '771 Provisional is broken, and Patent Owner “cannot rely on subject matter from the '771 Provisional for priority.” *Id.* at 22 (*citing Encyclopedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1351 (Fed. Cir. 2010) (where intermediate application failed to specifically reference first application, later applications could not claim priority to first); MPEP §211.02 (waiver of priority claim if “proper reference to the prior application is not included in the later-filed application.”)).

Third, Petitioner contends that Patent Owner “cannot rely on incorporation by reference of the '771 Provisional into any utility application before the '893 Application for written description support.” Prelim. Resp. 23–24. According to Petitioner, none of the utility applications preceding the '893 Application copied the subject matter disclosed in the '771 Provisional into their respective disclosures, and only a subset of those utility applications incorporated the '771 Provisional's disclosures by reference. *Id.* at 23–24 (*citing NRG Energy, Inc. v. Midwest Energy Emissions Corp.*, IPR2020-00832, Paper 17, 29–30 (PTAB Oct. 26, 2020); *Focal Therapeutics, Inc. v. Senorx, Inc.*, IPR2014-00116, Paper 8, 11–12 (PTAB Apr. 22, 2014); 37 C.F.R. § 1.57(d)).

Finally, Petitioner argues that, even if Patent Owner could meet the “technical requirements” for a priority claim to the ’771 Provisional, “the subject matter in the ’771 Provisional copied into the ’893 Application does not provide written description support” for the challenged claims. Pet. 24–25. Petitioner argues the ’893 Application and ’771 Provisional describe the use of neurotoxins to treat nasal conditions and *do not* describe any use of an RF generator “for supplying radiofrequency energy . . . to treat a target tissue in the nasal cavity and thus treat rhinitis” as claimed. *Id.* (citing challenged claim 1 (emphasis omitted)). Indeed, Petitioner contends, the purported priority applications only describe the use of energy to selectively porate target cells in order to facilitate the cells’ uptake of neurotoxin—the agent effectuating the treatment. Pet. 24–25 (citing, e.g., Ex. 1011 (’771 Provisional), 56 (describing “systems . . . which selectively porate target cells to enhance uptake of the toxin”); Ex. 1002 ¶¶ 69–75 (testimony of Dr. Bu-Saba on the differences between using RF energy for ablation and using energy for electroporation)).¹⁶

3. Patent Owner’s Contentions

Patent Owner contends that Petitioner’s emphasis on whether the claims are entitled to the priority benefit of the ’771 Provisional’s filing date

¹⁶ Petitioner contends that, in a separate set of applications that are substantially identical to, and incorporate the subject matter of, the ’771 Provisional, Patent Owner has pursued claims to “treating a nasal condition **with** not **without** neurotoxins.” Pet. 25 n.13 (citing, e.g., Exs. 1026, 1029, 1030)). Similarly, Petitioner argues that Aerin, the “named licensee of the ’077 patent” has represented during prosecution of another patent that “the **sole purpose** of applying energy described by [the ’771 Provisional] is to porate target cells to **enhance uptake of a nerve toxin.**” Pet. 25–26 (citing Ex. 1034, 786).

is misplaced. Prelim. Resp. 8–9. Patent Owner contends that the challenged claims of the '077 patent are entitled to a priority date of at least July 21, 2006, the filing date of the '090 Application, which issued as the '275 patent. *Id.* Patent Owner contends that “the '077 patent includes a clear chain of priority to the '090 application, and the challenged claims are fully supported by the '090 application,” thus “the '077 patent can claim priority to the '090 application and does not need to claim priority to the '771 provisional.” *Id.* at 9–12. Patent Owner further contends:

The '090 application not only claims the benefit of the '771 provisional and the '077 provisional, but it also incorporates by reference each provisional application into the specification in their entireties. As a result, every application in the priority chain includes a priority claim to the '090 application, which includes the disclosures of the '771 provisional and the '077 provisional.

Id. at 13–14 (arguing the priority chain to the '090 Application is “complete and intact” because each utility application in the chain claims priority to and “expressly incorporates by reference” the '090 Application). Patent Owner notes that “[t]he Federal Circuit has long held that patent applicants can incorporate references in their entirety.” *Id.* at 22 (citing *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906–07 (finding that the language “[reference] is incorporated herein by this reference” sufficiently incorporated the reference in its entirety); *Harari v. Lee*, 656 F.3d 1331, 1335–36 (Fed. Cir. 2011) (finding references were incorporated in their entirety based on the “broad and unequivocal language” that “[t]he disclosures of the two applications are hereby incorporate[d] by reference”)). Thus, Patent Owner contends, the subject matter of the '771 Provisional was properly added to the '077 patent’s Specification because the '090 Application includes the '771 Provisional’s disclosure in its entirety,

and “the ’077 patent is entitled to the priority date of the ’090 application and can incorporate material from that application without it being new matter.” Prelim. Resp. 14–17.

Finally, Patent Owner contends that the ’077 patent’s Specification, which “constitutes the specification [of] the ’090 application, including its incorporation by reference of the ’771 provisional” supports the challenged claims. *Id.* at 24 n.7. Patent Owner further notes that “the Petition itself asserts in Ground 4 that Deem, containing largely the same disclosure as the ’771 provisional and the ’090 application, satisfies each limitation of the claims.” *Id.* at 24–25 (asserting that Petitioner’s assertion of Deem as anticipating prior art is inconsistent with Petitioner’s position that the priority applications lack sufficient supporting disclosure). Thus, according to Patent Owner, “[b]ecause the ’077 patent has priority to the ’090 application and the claims are supported by the ’090 application, the claims have a priority date of July 21, 2006.” *Id.* at 26.

4. Discussion

Having considered the parties’ positions and evidence of record at this stage, we determine that the challenged claims are not entitled to a priority date earlier than October 22, 2019. We explain below.

We agree with Patent Owner that the ’077 patent has an unbroken priority claim to the ’090 Application, filed on July 21, 2006. Prelim. Resp. 9–13. We also agree that the introduction of subject matter from the ’771 Provisional into the ’893 Application, thereafter included in the ’077 patent’s Specification does not constitute new matter because the ’090 Application incorporates by reference the entirety of the ’771 Provisional and because the ’077 patent, along with each intervening non-provisional application, has an unbroken chain of priority to the

'090 Application. *Id.* at 11–20 (citing *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001) (an incorporated-by-reference “document becomes effectively part of the host document as if it were explicitly contained therein”); MPEP § 608.01(p) (“The limitations on material which may be incorporated by reference in U.S. patent applications which are to issue as U.S. patents do not apply to applications relied on only to establish an earlier effective filing date under 35 U.S.C. 119 or 35 U.S.C. 120.”); *see also Ex parte Maziere*, 27 USPQ2d 1705, 1706–07 (BPAI Jan. 26, 1993) (an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document)).¹⁷

Thus, the '077 patent has the right to make a priority claim to the '090 Application filed on July 21, 2006. That does not, however, end the inquiry because, for the challenged claims to be actually entitled to the priority benefit of the '090 Application's filing date, each of the relevant

¹⁷ On this record, we also tend to agree with the Board's reasoning in *Samsung* that “the prohibition of referencing ‘essential material’ in a ‘nested incorporation’ does not apply to applications which are relied on to establish an earlier effective filing date.” *Samsung Elecs. v. Acquis LLC*, IPR2021-00608, Paper 10 at 8–10 (PTAB Dec. 8, 2021) (analyzing MPEP § 608.01(p) and the distinction between Subparts I and II thereof, and how the Office has continued to apply Subpart II (including its instruction that incorporation by reference in an earlier application “is not critical in the case of a ‘benefit’ application”) even after implementation of 37 C.F.R. § 1.57). Prelim. Resp. 15–19 (citing *Samsung*, *Maziere*, and MPEP § 608.01(p)). Although the Board's decision in *NRG* may be read as somewhat in tension with this reasoning, patentee in that case appears to have not disputed whether Rule 1.57(c) applies when the issue was a priority benefit claim; and the panel in that case did not address MPEP § 608.01(p) and Subpart II as discussed in *Samsung. NRG Energy, Inc. v. Midwest Energy Emissions Corp.*, IPR2020-00832, Paper 17 at 29–30 (PTAB Oct. 26, 2020).

applications must provide written description support for those claims. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997) (explaining that, to claim “the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112”).

On the record before us, we do not discern how the Specification of the '077 patent, including the disclosure incorporated therein from the '771 Provisional, provides written description support for the challenged claims.¹⁸ Those claims are purportedly directed to treating rhinitis in the nasal cavity and comprise, *inter alia*, an RF generator “for supplying [RF] energy to the multiple [RF] electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.” Ex. 1001, claim 1. As noted by Petitioner, the Specification does not describe an apparatus that uses energy to treat rhinitis in the manner recited in the claims. Pet. 24–25. Rather, the Specification discloses the use of neurotoxins to treat nasal conditions, and more specifically, that neurotoxins are used to disrupt neural signals in the targeted tissue and, therein, disable mucus secretion by such tissues. *See, e.g.*, Ex. 1001, 3:31–40, 8:11–67, 21:46–22:6.¹⁹ In the Specification, energy

¹⁸ Patent Owner contends the Specification of the '077 patent comprises the disclosures of the '090 Application and '771 Provisional (which were copied into the '077 patent, and incorporated into the '090 Application). Prelim. Resp. 24 n.7. Accepting that premise for purposes of this Decision, our analysis here cites disclosures in the '077 patent's Specification as purportedly representative of the disclosures in the '771 Provisional, the '090 Application, and the other intervening ancestral applications.

¹⁹ The Specification describes, for instance, using botulinum toxin to block acetylcholine release from cells in the nasal membranes that are responsible for mucus hypersecretion even without energy-mediated delivery, but

is applied only to achieve cell membrane permeabilization or poration and effectuate the delivery of neurotoxin into target cells. *See e.g., id.* at 4:56–58, 8:10–28. Here, we note that claim 1 does not require the apparatus be configured for delivery of a neurotoxin for treatment of any nasal condition, but instead only supplying RF energy (via the RF generator) “to treat a target tissue in the nasal cavity and thus treat rhinitis.”

Patent Owner contends that the Specification of the ’077 patent supports the challenged claims “as it notes that energy used to ablate the tissue can be applied from a device separate from the device used to deliver a toxin.” Prelim. Resp. 24 (citing Ex. 1001, 9:1–17). The passage cited by Patent Owner, however, does not describe a device that provides treatment via ablation of tissues or that uses RF energy to provide treatment of rhinitis or any nasal condition. Rather, the passage describes applying energy to reversibly permeabilize or porate target cells to allow delivery of the neurotoxin. Specifically, the cited passage provides:

Any type of energy which is capable of reversibly permeab[i]lizing or porating the cell wall to allow passage of the toxin molecule, either whole toxin or preferably light chain fragment, into the cell cytoplasm may be applied to the cell membrane. Thus, energy may comprise various forms of

describing that use of energy to permeabilize the cells allows for more targeted delivery of the toxin. Ex. 1001, 21:46–56; 2:13–22 (explaining, as background, that acetylcholine is a neurotransmitter, the release of which is blocked by botulinum toxin); *see also id.* at 8:25–44 (disclosing that the “nasopharynx comprises a cluster of goblet cells which are responsible for mucus secretion and which are susceptible to the disabling mechanism of the botulinum toxin and other neurotoxins” and, further, by controlling the delivery area of the energy and toxin, “only those cells in the nasal membrane that are exposed to both the toxin and the applied energy will preferentially be permeabilized or porated to receive the toxin within the cytoplasm of the cell”).

electrical pulses, acoustic pulses, X-ray energy, microwave energy, or the like, and combinations thereof. Preferably, the energy will be either pulsed electrical energy of the type which is commonly used for cellular electroporation or will be ultrasonic energy of the type commonly employed for sonoporation of cells. The energy may be applied using the same catheters or other structures which are used for delivering the toxins. Alternatively, the energy may be applied using separate external or internal sources, such as using separate external ultrasonic transducers and/or ultrasound wave guides capable of delivering focused or unfocused ultrasound into the target tissues of the nasal cavity.

Ex. 1001, 9:1–17. That the energy and the toxin might be applied separately to the targeted tissues does not equate with the treatment contemplated by the challenged claims being provided without the toxin. And, it is not apparent that the passage above supports the use of energy *as the treatment*, only the use of energy to selectively porate target cells in order to facilitate the uptake of neurotoxin, a common theme throughout the Specification. *See e.g.*, Ex. 1001, 5:20–23 (“The systems further comprise an energy applicator for applying energy to the target cells under condition which cause poration of the cell membranes to enhance delivery of the toxins and/or their active fragments.”).

Petitioner provides *evidence* to the effect that the skilled artisan would understand that using energy to ablate tissue is distinctly different from a use of energy to porate cells, like described in the '077 patent's Specification. Pet. 24–25 (citing Ex. 1002 ¶¶ 69–75; Ex. 1059 ¶ 5). Petitioner's declarant Dr. Bu-Saba also testifies that the skilled artisan reading the disclosures of the Specification and asserted priority applications would not have understood that the inventors were in possession an apparatus that uses the energy itself—without a neurotoxin—to provide treatment like claimed.

Ex. 1002 ¶¶ 69–75 (testifying, for example, “there is no disclosure that describes treating a nasal condition (such as rhinitis or reducing mucus) without neurotoxin”). At this stage, Patent Owner provides only unsupported attorney argument in response, which is not persuasive. Thus, based on the current record, we tend to agree with Petitioner that the ’077 patent Specification fails to provide written description support for the challenged claims.

Accordingly, at this stage, we find persuasive Petitioner’s contention that the challenged claims are entitled to priority no earlier than October 22, 2019.

E. Asserted References

If, as determined above, the challenged claims are entitled to a priority date that is no earlier than October 22, 2019, then all the asserted references including Saadat and Deem qualify as prior art. Makower, Fang, Edwards, and Stern qualify as prior art without regard to that priority determination.

1. Saadat (Ex. 1003)

Saadat is a U.S. patent that issued June 4, 2019, from a nonprovisional application filed May 17, 2018. Ex. 1003, codes (22), (45).

Saadat is titled “Apparatus and Methods for Treating Rhinitis.” *Id.* at code (54). Saadat relates to “devices and methods for ablating regions of tissue such as through cryogenic ablation of tissue regions within the nasal cavity for treating conditions such as rhinitis.” *Id.* at 1:22–26. According to Saadat, rhinitis is “inflammation of the membranes lining the nose, characterized by nasal symptoms, including itching, rhinorrhea, and/or nasal congestion.” *Id.* at 2:16–18. Saadat reports that chronic rhinitis “is a leading cause for patients to seek medical care,” but “[m]edical treatment has been shown to have limited effects for chronic rhinitis sufferers and

requires daily medication use or onerous allergy treatments and up to 20% of patients may be refractory.” *Id.* at 2:18–24. Saadat discloses “[a]pparatus and methods for treating conditions such as rhinitis” in which “a distal end of a probe shaft is introduced through the nasal cavity where the distal end has an end effector with a first configuration having a low-profile which is shaped to manipulate tissue within the nasal cavity.” *Id.* at Abstract.

Saadat describes devices and methods for ablating one or more branches of the Posterior Nasal Nerves (“PNN”) which innervate the nasal turbinates to reduce or eliminate rhinitis. Ex. 1003, 3:10–14. According to Saadat, “[t]he nasal turbinates are three bony processes that extend inwardly from the lateral walls of the nose and are covered with mucosal tissue” and “serve to increase the interior surface area of the nose and to impart warmth and moisture to air that is inhaled through the nose.” *Id.* at 1:43–47. Saadat explains that “[t]he mucosal tissue that covers the turbinates is capable of becoming engorged with blood and swelling or becoming substantially devoid of blood and shrinking, in response to changes in physiologic or environmental conditions.” *Id.* at 1:47–51. Saadat discloses that ablating the PNN “leads to a decrease in or interruption of parasympathetic nerve signals that contribute to congestion and rhinorrhea in patients with chronic rhinitis (allergic or vasomotor).” *Id.* at 3:6–10.

Saadat discusses various types of surgical probes and their use for ablating PNN, including an electrosurgical probe apparatus. Saadat explains that the electrosurgical probe apparatus includes a handle at the proximal end, and a probe shaft with a radiofrequency (RF) ablation element that comprises at least one radiofrequency (RF) electrode mounted in the vicinity of the distal end of the shaft and an electrical connector in the vicinity of the handle configured to connect the RF ablation element to a source of

radiofrequency energy. Ex. 1003, 10:16–26, 10:41–11:14. The RF ablation element may comprise “a monopolar electrosurgical configuration comprising one or more electrodes” or “a bipolar electrosurgical configuration comprising two or more electrodes,” and may be “disposed in the vicinity of the distal end of the shaft on a cylindrical, ‘J’ shaped, ‘U’ shaped or ‘T’ shaped structure.” *Id.* at 10:41–11:14. Figure 20E, reproduced below, “is a schematic illustration of the distal end of an alternative embodiment of an RF ablation probe comprising a bi-polar electrode ablation element on a user deployable ‘T’ shaped structure.” *Id.* at 15:18–21.

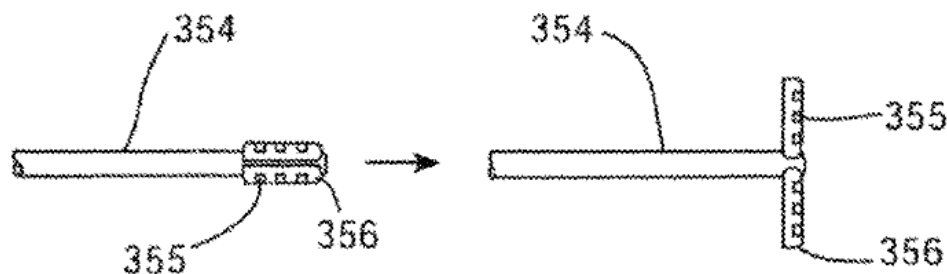


Figure 20E

The RF ablation probe 338 depicted in Figure 20E includes a distal end 354 which comprises “a bi-polar electrode ablation element 355 on a user deployable ‘T’ shaped structure 356.” *Id.* at 31:10–14. Saadat explains that the user deployable “T” shaped structure 356 “is comprised of two halves which can alternately be collapsed and deployed as in FIG. 20E. The two halves of the electrode structure 356 are pivoted to allow them to move laterally relative to the catheter shaft 354.” *Id.* at 31:14–18.

Saadat’s Figure 30, reproduced below, “is an in situ illustration of the ablation of the posterior nasal nerve using a generic ‘T’ tipped ablation device 448.” Ex. 1003, 33:41–43.

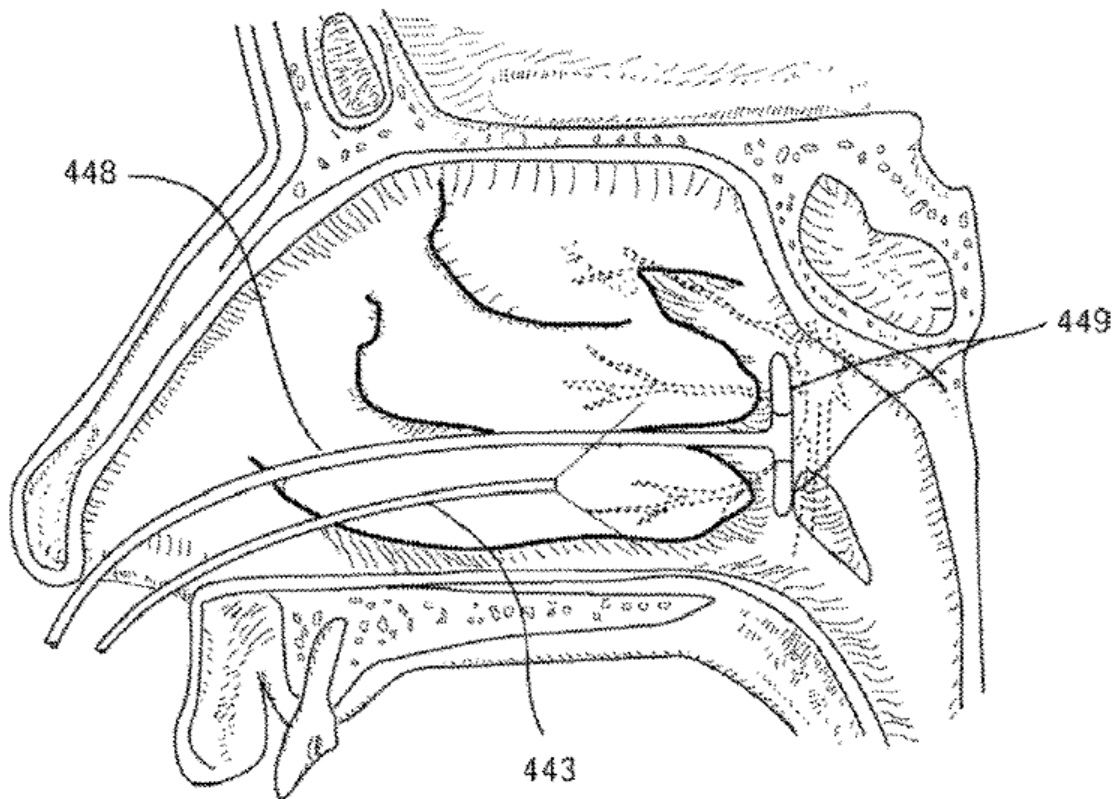


Figure 30

Figure 30 depicts an endoscope 443 and a generic “T” tipped ablation device 448. *Id.* at 33:41–49. The endoscope 443 “provides the surgeon an image for positioning ablation element 442 at the target location, and a means for monitoring the ablation.” *Id.* at 33:46–49. The ablation device 448 includes ablation elements 449, “which could be cryo ablation elements, RF ablation elements, or some other type of thermal ablation elements.” *Id.* at 33:43–46).

2. *Deem (Ex. 1004)*

Deem is a U.S. patent application that published January 24, 2008. Ex. 1004, codes (43). Deem claims priority, as a continuation-in-part application, to the '090 Application (discussed *supra* Section IV.D).

Deem is titled “Methods and Systems for Toxin Delivery to the Nasal Cavity.” Ex. 1004, code (54). Deem “relates to methods and systems for delivering toxins, such as *botulinum* toxin light chain fragments, to target cells in a nasal cavity.” *Id.* ¶ 3. Deem’s invention “provides treatments for any disease or condition for which rhinorrhea is a result or symptom,” including rhinitis. *Id.* ¶¶ 11–12. Deem defines rhinorrhea as “the effluence of mucus from the lining of the nasal passages, nasopharynx, or paranasal sinuses.” *Id.* ¶ 12. Deem explains that “[r]hinitis, which includes the symptoms of rhinorrhea, is a condition resulting from inflammation and swelling of the patient’s mucus membranes which line the nasal cavity.” *Id.* ¶ 4. According to Deem, “[w]hile numerous treatments for rhinitis have been proposed over the years, no single treatment is optimum for all patients or all conditions.” *Id.* ¶ 5. For example, antihistamines may be used to block the inflammatory response; however, “many antihistamines can cause drowsiness, have a limited duration of effect, and present the patient with an on-going cost to continuously purchase the drugs.” *Id.* According to Deem,

a longer term therapy for rhinitis which relies on the use of *botulinum* toxin (“BoNT”) for blocking mucus production by mucus-producing cells in the nasal membrane has been proposed. *Botulinum* and other neurotoxins are capable of disabling adrenergic cells, including epithelial or goblet cells which are responsible for the majority of mucus production in the nasal cavity membrane.

Id. ¶ 6. Deem discloses that “it would be desirable to provide improved methods and systems for delivering toxins, such as *botulinum* and active *botulinum* fragments, to the nasal membrane of a patient, particularly a patient suffering from rhinitis or other conditions associated with nasal inflammation and conditions, such as sinus headaches and migraine headaches.” *Id.* ¶ 8.

Deem reports that

[a]ccording to the present invention, *botulinum* toxin, ricin, exotoxin A, diphtheria toxin, cholera toxin, tetanus toxin, other neurotoxins, and active fragments thereof are delivered to a patient's nasal membrane while applying energy to target cells within the membrane under conditions which cause a reversible (or in some instances non-reversible) poration of the cell membranes to enhance delivery of the toxin into the cells.

Ex. 1004 ¶ 15. The toxin may be introduced to any portion of the nasal cavity, including “the nasopharynx which is at the back of the nasal passage” and “comprises a cluster of epithelial or goblet cells which are responsible for mucus secretion and which are susceptible to the disabling mechanism of the botulinum toxin and other neurotoxins.” *Id.* Deem explains that “[b]y controlling the delivery area of both the toxin delivery and the energy delivery, the methods and apparatus of the present invention can more specifically target the epithelial or goblet and other recipient cells of interest while minimizing the amount of toxin which enters non-targeted cells” such that “only those cells in the nasal membrane which are exposed to both the toxin and the applied energy will preferentially be permeab[i]lized or porated to receive the toxin within the cytoplasm of the cell.” *Id.* ¶ 16; *see also id.* ¶¶ 17, 66.

According to Deem,

the terms ‘poration’ and/or ‘permeab[i]lization’ include various forms of electrically-mediated poration, such as the use of pulsed electric fields (PEFs), nanosecond pulsed electric fields (nsPEFs), ionophoresis, electrophoresis, electropermeabilization, as well as other energy mediated permeabilization, including sonoporation (mediated by ultrasonic or other acoustic energy), and/or combinations thereof, to create temporary pores in a targeted cell membrane.

Ex. 1004 ¶ 71. Deem also discloses that the terms “electrode” and “energy source” include “the use of various types of energy producing devices, including x-ray, radiofrequency (RF), DC current, AC current, microwave, ultrasound, adapted and applied in ranges to produce membrane permeabilization in the targeted cell.” *Id.*

Deem depicts an example of a system utilizing an electroporation catheter for selective electroporation of targeted cells in Figure 5, reproduced below.

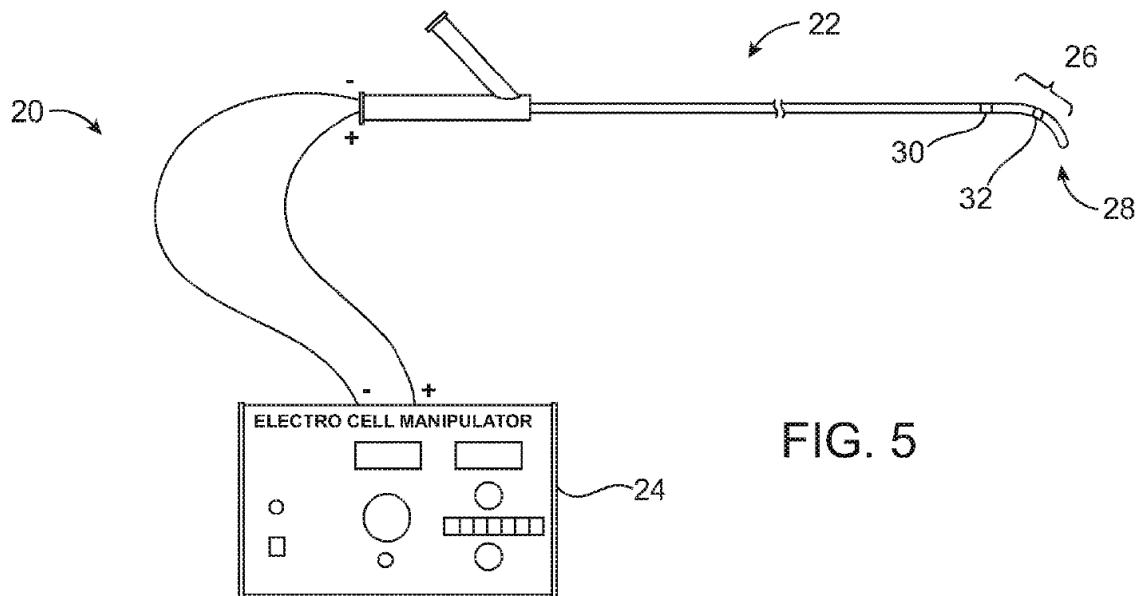


FIG. 5

Figure 5 is an embodiment of a delivery device of Deem’s invention “utilizing multiple energy transmission elements and an energy transmission system.” Ex. 1004 ¶ 28. The delivery device includes an electroporation catheter system 20 which comprises a pulse generator 24 and an electroporation element 28 at the distal region thereof. *Id.* ¶ 90. The pulse generator 24 is “electrically connected to a catheter 22 having a proximal end and a distal region 26 adapted for minimally invasive insertion into the desired region of the body.” *Id.* The electroporation element 28 includes “a first electrode 30 and a second electrode 32 operatively connected to the

pulse generator for delivering the desired number, duration, amplitude and frequency of pulses to affect the targeted cells.” *Id.*

3. *Makower (Ex. 1005)*

Makower is a U.S. patent application that published October 27, 2005. Ex. 1005, code (43).

Makower is titled “Devices, Systems and Methods for Diagnosing and Treating Sinusitis [*sic*] and Other Disorders of the Ears, Nose and/or Throat.” *Id.* at code (54). Makower “relates generally to medical devices and methods and more particularly to minimally invasive, catheter based devices, systems and methods for treating sinusitis and other ear, nose & throat disorders.” *Id.* ¶ 1. Makower states that “[t]he term ‘sinusitis’ refers generally to any inflammation or infection of the paranasal sinuses.” *Id.* ¶ 8.

Makower explains that “[t]he sinuses consist of a series of cavities connected by passageways, ultimately opening into the nasal cavity.” Ex. 1005 ¶ 16. The “passageways and cavities are formed by bone, but covered in mucosa.” *Id.* Makower reports that “[i]f the mucosa of one of these passageways becomes inflamed for any reason, the cavities which drain through that passageway can become blocked” such that “the primary target for sinus therapy is the passageway, with the primary goal to regain drainage.” *Id.* According to Makower, “focus on the passageway and the use of flexible instrumentation suggests an entirely new approach to sinus intervention: one utilizing flexible catheters and guidance tools, with passageway and cavity modifying devices capable of being delivered with minimal damage to the surrounding tissues.” *Id.*

One such intervention is surgery to reduce the size of the inferior turbinates and the associated mucosa or soft tissue. Makower explains that

[s]urgery to reduce the size of the inferior turbinates can be accomplished with endoscopic visualization (with magnification where desired) and is typically performed with the patient under general anesthesia. An incision is typically made in the mucosa that lines the turbinate to expose the underlying bone. Some quantity of the underlying bone may then be removed. If selective removal of some of the mucosa or soft tissue is also desired, such soft tissue can be debulked or removed through by traditional surgical cutting or by the use of other tissue ablation or debulking apparatus such as microdebriders or lasers. Less frequently, chronically enlarged inferior turbinates have been treated by cryotherapy. It is typically desirable to remove only as much tissue as necessary to restore normal breathing and drainage, as removal of too much tissue from the turbinates can impair the ability of the turbinates to perform their physiological functions of warming and humidifying inspired air and conserving warmth and moisture from expired air.

Ex. 1005 ¶ 30.

Another example of an intervention disclosed in Makower is laser or radiofrequency turbinate reduction. According to Makower, “[i]n cases where it is not necessary to revise the bone that underlies the turbinate, the surgeon may elect to perform a laser or radiofrequency procedure designed to create a coagulative lesion in (or on) the turbinate, which in turn causes the soft tissue of the turbinate to shrink.” *Id.* ¶ 39. Makower discloses that “[o]ne example of a radio frequency procedure that may be used to shrink enlarged inferior turbinates is radiofrequency volumetric tissue reduction (RFVTR) using the Somnoplasty® system (Somnus Medical Technologies, Sunnyvale, Calif.)” which “includes a radio frequency generator attached to a probe.” *Id.* ¶ 40. Makower explains that

[t]he probe is inserted through the mucosa into the underlying soft tissue of the turbinate, usually under direct visualization. Radiofrequency energy is then delivered to heat the submucosal tissue around the probe, thereby creating a submucosal

coagulative lesion while allowing the mucosa to remain intact. As the coagulative lesion heals, the submucosal tissue shrinks thereby reducing the overall size of the turbinate.

Id.

Makower provides “methods wherein one or more flexible catheters or other flexible elongate devices as described herein are inserted in to the nose, nasopharynx, paranasal sinus, middle ear or associated anatomical passageways to perform an interventional or surgical procedure.” Ex. 1005

¶ 43. Makower discloses that its

invention provides a variety of apparatus that may be inserted into the nasal cavity, paranasal sinus, nasopharynx or middle ear to perform diagnostic or therapeutic procedures. These devices may be delivered through or incorporated into flexible catheters or flexible rod-like shafts. Such flexible construction allows these devices to be delivered and positioned to perform the desired diagnostic or therapeutic procedures with minimal trauma to other tissues, as can result from the insertion of rigid scopes and rigid instruments in accordance with the methodology of the prior art.

Id. ¶ 161.

An example of a tissue shrinking electrode device being used in accordance with Makower’s invention is shown in Figure 5H, reproduced below.

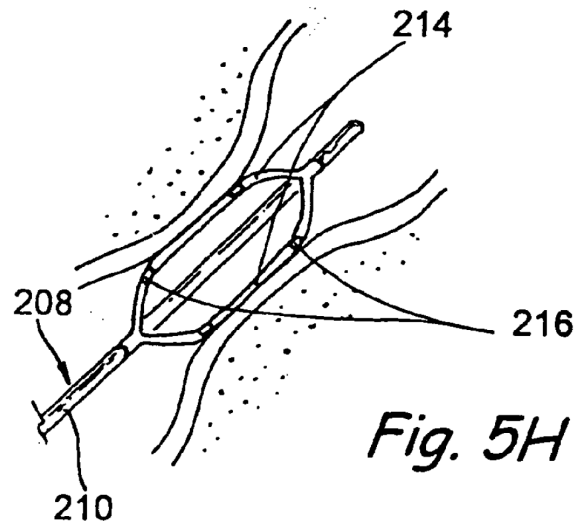


Figure 5H depicts “an electrosurgical device 208 comprising a flexible shaft 210 (e.g., a catheter or solid shaft) having arched strut members 214 attached thereto.” Ex. 1005 ¶ 187 (emphasis omitted). The strut members 214 may be of fixed configuration or collapsible and expandable, and include electrodes 216 that “may be bipolar, monopolar or facilitated by any other suitable form of energy such as a gas or plasma arc.” *Id.* Makower discloses that “sensing elements may also be attached to the catheter and/or strut members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.).” *Id.* According to Makower, “[i]n operation, the device 208 is advanced into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. Thereafter, current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated.” *Id.* (emphasis omitted).

4. *Fang (Ex. 1006)*

Fang is an article titled “Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis.” Ex. 1006, 876.²⁰ Fang discusses the results of a study “[t]o evaluate the therapeutic effects of nasal endoscopic surgery combined with multiple radiofrequency in the treatment of perennial allergic rhinitis.” *Id.* According to Fang, “[s]ixty-three patients with perennial allergic rhinitis whose symptoms failed to be controlled by medication received nasal endoscopic surgery for submucous resection of the nasal septum combined with radiofrequency ablation of the bilateral sphenopalatine foramen, anterior ethmoidal nerve, and inferior nasal concha.” *Id.* “[A]nother 20 patients with the same disease who underwent nasal septum surgery alone were selected as the control group.” *Id.* After the surgeries, “efficacy was evaluated according to the evaluation criteria for allergic rhinitis” (*id.*) and “[a]ll the patients were followed up for 2 years, and no antihistamines or corticosteroids were used for treatment during the observation period” (*id.* at 877).

Fang reports that

[a]t 1 month after operation, the rate of excellent recovery was 92.1% (58/63), the efficacy rate was 7.9% (5/63), and the total efficacy rate was 100%. At 1 year after operation, the rate of excellent recovery was 88.9% (56/63), the efficacy rate was 7.9% (5/63), the rate of no efficacy was 3.2% (2/63), and the total efficacy rate was 96.8% (61/63). At 2 years after operation, the rate of excellent recovery was 82.6% (52/63), the efficacy rate was 12.7% (8/63), the rate of no efficacy was 4.8% (3/63), and the total efficacy rate was 95.2% (60/63). Compared with

²⁰ Fang purports to be the Chinese to English translation of the original article; Petitioner submits a declaration from the translator (Ex. 1073) attesting to the translation’s accuracy, and testimony from June Munford (Ex. 1070 ¶¶ 39–56) on the article’s public availability by July 20, 2005.

patients in the control group who underwent only nasal endoscopic surgery for submucous resection of the nasal septum, the total efficacy rate ($P < 0.01$ for excellent recovery + Efficacy) at 1 and 2 years after the surgery was significantly improved, with statistical significance.

Ex. 1006, 876.

According to Fang,

[t]he use of radiofrequency technique completely blocks the parasympathetic pathway of the nasal mucosa, reduces the vascular tension, reduces glandular secretion, and thus achieves the therapeutic purposes. Pterygoid canal neurotomy alone or/and anterior ethmoidal neurotomy or inferior turbinate treatment preserves 1-2 parasympathetic pathways in the source and distribution of parasympathetic nerves in the nasal mucosa. However, due to the presence of allergic reaction arcs, the postoperative effect is poor and the recurrence rate is high. For the patients in this group, all the nasal mucosal parasympathetic pathways, including the posterior ganglionic fibers of the sphenopalatine nerve, the parasympathetic fibers of the anterior ethmoidal nerve, and the cholinergic ganglia within the inferior turbinate mucosa were blocked. The allergic reflex arc was completely relieved, thus achieving stable and reliable results.

Id. at 877.

5. *Edwards (Ex. 1008)*

Edwards is a U.S. Patent that issued on February 11, 2003. Ex. 1008, code (45). Edwards teaches an apparatus for ablating a nasal concha. *Id.* at Abstr., 1:22–26 (describing a method and apparatus for reducing the volume of turbinates to reduce nasal airway obstruction). Edwards discloses that the apparatus may comprise a catheter body and energy delivery device, and further that an energy source supplies energy, “preferably RF energy which ablates the turbinate by heat and cell destruction.” *Id.* at 8:17–25, 8:47–9:13 (describing an RF signal generator for generating pulsed RF energy and a processor for controlling said generator), Fig. 6.

6. *Stern (Ex. 1009)*

Stern is a U.S. Patent that issued October 8, 1996, and relates to a bipolar/monopolar endometrial ablation device and method. Ex. 1009, codes (45), (57).

Stern discloses an apparatus with an array of surface electrodes. *Id.* at Fig. 17, 2:36–40. According to Stern, the apparatus provides for selective delivery of bipolar RF energy to chosen pairs of an array of separate electrodes. *Id.* at 2:36–40; *see also id.* at 12:41–132:2, Fig. 15 (showing circuitry for pairs of bipolar RF electrodes connected to a voltage source).

F. *Ground 1: Anticipation by Saadat*

Petitioner contends that claims 1–3, 5–8, and 11 are anticipated by Saadat.²¹ Pet. 31–46. In support, Petitioner provides a detailed discussion explaining how the claimed subject matter is disclosed by Saadat “arranged as in the claims.” *Id.* (citing *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016)). Petitioner’s contentions are also supported by the Declaration of Dr. Bu-Saba. Ex. 1002 ¶¶ 83–127.

More specifically, Petitioner contends that Saadat discloses an RF ablation probe configured for use in a nasopharyngeal passage of a patient for the ablation of nasal tissues by applying RF energy. Pet. 32–39 (citing Ex. 1002 ¶¶ 84–99). As Petitioner explains, Saadat describes, for example, a posterior “T”-shaped ablation device that may be positioned to target the posterior nasal nerve. *Id.* (citing Ex. 1003, Fig. 20E, 33:41–49; Ex. 1002

²¹ The heading for Ground 1 in the Petition lists claims 1–8 and 11 as anticipated by Saadat. Pet. 31; *compare* Ex. 1002 ¶ 83 (Bu-Saba Declaration listing claims 1–3, 5–8, and 11 under Ground 1). But claim 4 is not addressed under Ground 1 and, instead, is addressed under Ground 3 as allegedly obvious over Saadat and Stern. Pet. 50–56.

¶ 86). Petitioner cites Saadat’s teaching that “[a]blating these nerves leads to a decrease in or interruption of parasympathetic nerve signals that contribute to congestion and rhinorrhea in patients with chronic rhinitis.” *Id.* at 33 (citing Ex. 1003, 1:62–66; 3:6–14)). Petitioner, with the supporting testimony of Dr. Bu-Saba, further explains how Saadat describes a probe handle and shaft that meets claim 1’s recitations of an elongate body with proximal and distal portions, that the distal portion comprises multiple RF electrodes, and also includes an RF generator coupled to the proximal portion of the elongate body for supplying the RF energy to the probe’s electrodes to ablate the nerves in the nasal cavity and treat rhinitis as otherwise claimed. Ex. 1002 ¶¶ 93–112; Ex. 1003, Figs. 20A, 20E, 30; *see also id.* at 3:6–14, 10:16–11:14, 30:34–49.

Patent Owner, at this time, does not make any arguments addressing Petitioner’s substantive showing on what Saadat describes and whether Saadat anticipates the claimed subject matter, which showing we find sufficient for institution purposes. *See generally* Prelim. Resp. Patent Owner argues only that Saadat is not prior art if the claims are entitled to the priority benefit of the ’090 Application’s filing date on July 21, 2006. *Id.* at 26. On the present record, we determine that the challenged claims are entitled to an effective filing date no earlier than October 22, 2019. *See supra* Section IV.D. Saadat is a U.S. patent that issued June 4, 2019, from a nonprovisional application filed May 17, 2018. Thus, under 35 U.S.C. § 102(a)(1), Saadat qualifies as prior art to the challenged claims.

In view of the foregoing, we determine that Petitioner has established a reasonable likelihood of showing that Saadat anticipates at least one of the claims 1–3, 5–8, and 11 of the ’077 patent.

G. Grounds 2 & 3: Obviousness over Sadaat and Stern

Petitioner argues that claims 3 and 11 would also have been obvious over Saadat (Ground 2) and that claim 4 would have been obvious over Saadat and Stern (Ground 3). Pet. 46–56. Petitioner provides unrebutted evidence, including the testimony of Drs. Bu-Saba and Martin, to support its assertions, which we find sufficient for institution purposes. *Id.*; Exs. 1002 ¶¶ 128–150; Ex. 1007 ¶¶ 50–77.

Patent Owner’s argument about Grounds 2 and 3 is, at this stage, limited to arguing that Saadat is not prior art. Prelim. Resp. 26. We rejected that argument as explained above (Section IV.D).

Based on this preliminary record, Petitioner has established a reasonable likelihood that it will prevail under Grounds 2 and 3.

H. Ground 4: Anticipation by Deem

Petitioner contends that claims 1–8 and 11 are anticipated by Deem “if the Board confirms an October 22, 2019 priority date and [the Board] finds the ’771 Provisional provides written description support for the claims.” Pet. 56–66. According to Petitioner, based on the similarities between Deem and the ’771 Provisional, the “identical disclosures in Deem would anticipate the Challenged Claims for identical reasons.” *Id.* at 56.

As discussed above, we do not find that the Specification of the ’077 patent, which contains the relevant subject matter disclosed in the ’771 Provisional, provides written description support for the challenged claims. Thus, following Petitioner’s logic, the allegedly “identical” disclosures in Deem do not anticipate the claims. Pet. 56. Based on the present record, we determine that Petitioner has not shown that it is reasonably likely to prevail on Ground 4.

I. Grounds 5 & 6: Obviousness over Makower, Fang, Edwards, and Stern

Petitioner argues that claims 1–3, 5–8, and 11 would have been obvious over Makower, Fang, and Edwards (Ground 5), and argues that claim 4 would have been obvious over Makower, Fang, Edwards, and Stern (Ground 6). Pet. 56–95.²² To support its contentions, Petitioner provides a detailed analysis addressing how the combined art discloses each element of the challenged claims. *Id.* Petitioner reasons, *inter alia*, that a person of ordinary skill would have been motivated to combine the cited references “to apply Fang’s method (disrupting neural activity using ablation) with Makower’s device (electrosurgical device for the nasopharynx) to treat rhinitis.” *Id.* at 78–79; *see also id.* at 82–85 and 93–95 (citing rationale to use well-known RF generator and electrode arrangements for ablation procedures as taught in Edwards and Stern). Petitioner’s contentions are supported by the declarations of Drs. Bu-Saba and Martin. Ex. 1002 ¶¶ 151–224; Ex. 1007 ¶¶ 78–108.

Patent Owner argues that a skilled artisan would not have been motivated to combine Makower and Fang. Prelim. Resp. 37–43. Patent Owner argues, for example, that Makower and Fang have different objectives—Makower’s alleged non-surgical therapeutic devices versus Fang’s alleged emphasis on surgical interventions—and their teachings would not, therefore, be combined. *Id.* at 38–39.

Whether a skilled artisan would have been motivated to combine the art’s teachings with a reasonable expectation of success in arriving at the

²² Petitioner’s heading for Ground 5 includes claim 4, but that claim is not otherwise addressed as part of Ground 5. Rather, the unpatentability of that claim for the Makower-based challenge is addressed under Ground 6.

claimed subject matter is a fact-intensive inquiry. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006) (“The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact”); *Par Pharm., Inc. v. TWi Pharma., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) (“The presence or absence of a reasonable expectation of success is also a question of fact[.]”). Petitioner supports its challenge with evidence-backed reasoning, including the testimony of Dr. Bu-Saba, and Patent Owner’s responsive attorney argument is unavailing at this stage. *See, e.g.*, Ex. 1002 ¶¶ 179–187 (testifying, *inter alia*, that Makower and Fang both teach applying RF energy to the nasopharyngeal passage to disrupt nerves and treat rhinitis, with Makower detailing an electrosurgical device and uses thereof and Fang elaborating on a therapeutic result that would be expected from use of such a device, thus suggesting the skilled artisan’s consideration of the art’s combined teachings).

We will revisit Petitioner’s asserted reasons for combining Makower and Fang as appropriate on a fully-developed record. At this stage, however, Petitioner has put forth sufficient evidence and reasoning to meet its institution burden and proceed to trial, especially as we have already concluded that Petitioner is reasonably likely to prevail on at least one claim challenged in each of Grounds 1–3, and all grounds must, therefore, be included in trial. *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018) (holding that, if trial is instituted, the Board must institute on all grounds raised in the petition). *See* 37 C.F.R. § 42.208(a) (“When instituting post-grant review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”); *see also* Guidance on the impact of SAS on AIA trial proceedings, available at <https://www.uspto.gov/patents/ptab/trials/guidance-impact-sas>

aia-trial (“If the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition.”).

V. CONCLUSION

There is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. We decline to deny the Petition on a discretionary basis. We institute *inter partes* review on all challenged claims under the grounds raised in the Petition. *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (explaining that institution of *inter partes* review “require[s] a simple yes-or-no institution choice . . . embracing all challenges included in the petition”); 37 C.F.R. § 42.108(a).

Any argument not raised in a Patent Owner Response to the Petition, or as permitted in another manner during trial, shall be deemed waived even if asserted in the Preliminary Response. *See In re NuVasive, Inc.*, 842 F.3d 1376, 1380–81 (Fed. Cir. 2016) (holding Patent Owner waived an argument addressed in the Preliminary Response by not raising the same argument in the Patent Owner Response).

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of all challenged claims of the ’077 patent is instituted on all grounds of unpatentability set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.4, notice is given of institution of trial commencing on the entry date of this decision.

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